

Service Provider Technical Questions for NIH

February 18, 2004

1. I can't find any recent documentation on what the specific content-id labels for PDF attachments sent me in the application MIME package. Specifically, what strings should be used to set the content-id of the PI cover letter, revised/supplemental application introduction, and the four attachments representing sections A through D of the research plan?

Answer

Refer to: *Appendix 4: Skeleton of the Grant Application Package* in the following document:

***Packaging an Electronic Grant Application*—This document is available on the NIH eRA Partnership Information website.**

2. The validations document specifies that the mandatory Phase3ClinicalTrialQuestion element be validated as "Y", "N", or "X", but the XML schema requires a boolean. What would an "X" value represent?

Answer:

"Y, N, and X" should not be listed in the validations document. The allowable values should be True or False. We will correct the validations document to reflect this and re-post the document by the end of the week.

3. In the validations document, the IACUCAApprovalPending element is a String type with length of 7, but the XML schema simply takes an indicator. Can the application simply have a checkbox to indicate approval pending?

Answer:

Yes, it would be reasonable for the user interface to present a checkbox to the applicant. The only significant information for the XML stream is that the IACUCAApprovalPending element be supplied to indicate the applicant's choice. It is the presence, and not the actual content of the tag that is important because the tag value is not shown on the grant image. The very presence of the tag (regardless of its content) will cause the word "Pending" to appear in the generated grant image.

4. The PI on this proposal has entered "Principal Investigator," which we are sending as `<nih:RoleOnProject>Principal Investigator</nih:RoleOnProject>`, and we're receiving this error:

"There are no PI or PD roles included. Please provide at least one role of PI or PD."

I have three comments:

1. This does not mesh with the Validation Table which says: "Must be one and only one component with a role of PI or PD. There cannot be both a PI and a PD."
2. We do need to know who is initiating the proposal but perhaps RoleOnProject is not the place to enforce this. The designation of PI/PD is not necessarily the same as RoleOnProject. On every proposal, we know who the PI is; their data are handled separately from other key personnel and with good reason (and this is recognized in the structure of "Instructions for Collecting Person

Information".) There is no RoleOnProject requested in order to designate them as Principal Investigator or Program Director. Why then require this in the KeyPerson.RoleOnProject section?

3. PI is one acceptable entry for RoleOnProject, I think we should accept PI, PD, Principal Investigator and Program Director as well. Why force people to abbreviate if they don't want to?

The schema have been relaxed to accept more descriptive phrases for most key personnel and I submit the same should be done for the PI. The PI may well have a different role on the project, as we pointed during Phase 1, and this is part of why there was so much discontent. Remember, the published guidelines for the 398 state: "Under role on the project, indicate how the individual will function with regard to the proposed project." The PI is supposed to describe their lab work, etc.

Answer:

The validation error occurs because the expected representation (literally, "PI" or "PD") must be identified in this section for the principal investigator or program director. Originally, this portion of the application was required to be entirely encoded, with either PI (for principal investigator) or KP (for other key personnel). For this pilot, we did relax the coding requirement for other key personnel, allowing a fairly limited amount of free-form text instead. This was done because KP does not really convey a meaningful role at all, and we have not yet defined a more specific set of category codes that can be used to report on non-PI key personnel in this section.

However, this concern did not seem to apply to the PI or PD. This category is descriptive enough for the purposes of the key personnel section, so the requirement to have this individual identified unambiguously using the PI or PD designation was maintained. The assertion in this comment that a PI may have a different role on the project is a bit confusing, but perhaps it is just the wording. The PI may have some other role on the project in addition to being the PI, but he/she is still the PI. And since it is a concise indication of each person's primary role (such as "PI") that we're really looking for on page 2, we are receiving sufficient information for the PI in this case.

Nonetheless, these comments will be considered as we chart our course for subsequent pilots. These comments touch upon valid issues, but they are issues that cannot be addressed or resolved in the timeframe of the current pilot. Therefore, we will need to defer a final response until a later time. For practical purposes, the rules we currently have in place regarding the PI's role-on-project will be retained for this phase.

5. I've just checked two PPFs (my own and that of another PI) and "HOM" appears as the MailStopCode in both profiles. Why?

Answer:

For the time being, ignore the MailStopCode that is being returned by the Person Information Service. It is not a mandatory field in the application data stream. It is not maintained in the PPF as a separate data item anyway, so it most likely will be removed from the response message in the next pilot phase.

6. In your “NIH eRA CGAP Support for Service Providers Terms and Conditions” published on 1/29/04, Trading Partner Identifier (page 4) is described as “The identifier of the registered system that request the information.” Is this the DUNS number, IPF code, or Exchange Userid we submitted to NIH for the July 2003 Pilot?

Answer:

TRADING_PARTNER_ID is the DUNS number.